

REMARKS

In the Office Action dated March 26, 2009, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- Group I. Claims 1-19 and 21, drawn to a genetic vaccine construct comprising an avipoxvirus that expresses a prostate specific polypeptide or a derivative thereof and optionally a sequence of nucleotides encoding an immunostimulatory peptide and to a hybridization probe.
- Group II. Claim 20, drawn to an antibody capable of acting as a marker for the genetic vaccine construct and recognizes epitopes uniquely formed in expression product of the genetic construct using avipox vector that encodes a prostate specific polypeptide and optionally encodes an immunostimulatory peptide.
- Group III. Claims 22-23 and 26-34, drawn to a method for stimulating or enhancing a prostate cell specific immune response in a subject using an avipox vector that encodes a prostate specific polypeptide and optionally encodes an immunostimulatory peptide.
- Group IV. Claims 24-25 and 26-34, drawn to a method for immunotherapy and/or immunoprophylaxis of a prostate cancer in a subject using an avipox vector that encodes a prostate specific polypeptide and optionally encodes an immunostimulatory peptide.

Further, the Examiner states that should Group I be elected, Applicants are required to elect a single species of cytokine among those recited in claims 8 and 9, i.e., IL-2, IL-12, TNF-alpha, IFN-gamma, IL-6, IL-7 or GM-CSF. The Examiner contends that the species are independent or distinct because they are structurally distinct.

In order to be fully responsive to the Examiner's restriction, Applicants provisionally elect Group I, claims 1-19 and 21, for continued prosecution. Applicants further provisionally elect IL-2 as the species for continued prosecution. Within the claims of Group I, claims 2-9 and

11-19 are generic relative to the elected species, and claim 10 reads specifically on the elected species.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner alleges that the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, there is no common technical feature that links all groups. Specifically, citing WO 1997/03203, WO 1998/046769, Fong et al. (*J. Immunol.* 1997, 159: 3113-3117) and Kass et al. (*Cancer Res.* 61: 206-214, 2001), the Examiner alleges that the prior art discloses a feature linking technical claims 1-34, i.e., a genetic vaccine construct comprising an avipox virus vector which expresses a prostate specific polypeptide. Therefore, the Examiner contends that the invention as a whole thus lacks unity under PCT rules. Further, the Examiner states that the mode of operation and the effects evaluated in each of the groups are distinct and different from the other. Therefore, a

search and examination for the patentability of the above groups together would generate an undue search burden on the examiner.

Applicants respectfully submit that unity of invention, not novelty, is the issue at hand. Applicants should be given the opportunity to argue the merits during prosecution, i.e., whether the claims are novel over prior art. Restriction of the claims at this stage would deny Applicants such an opportunity.

Further, Applicants respectfully submit that Groups III and IV are directed to methods of using the genetic vaccine of Group I. The PCT Rules specifically permit product claims and process of use claims to be examined together in one application. See PCT Applicant's Guide regarding Rule 13.2, Section 206, Paragraphs 130 and 131, setting forth different categories of claims that can be combined under the unity of invention requirement. See, also, the provisions of 37 C.F.R. §1.475(b)(2). Therefore, Applicants request that Groups III-IV be examined together with Group I.

With respect to species election, Applicants simply remind the Examiner of the provision of MPEP §809.02(a), i.e., upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups and species, one from another, as presented by the Examiner.

Accordingly, it is respectfully submitted that the present claims satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all pending claims.

Respectfully submitted,

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